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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/609,206

06/26/2003

Daniel J. Potter

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SJM/AFD-WILEY

14901 DEVEAU PLACE

MINNETONKA, MN 55345-2126

EXAMINER

YABUT, DIANE D

ART UNIT

PAPER NUMBER

3734

MAIL DATE

DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/609,206	<b>Applicant(s)</b> POTTER ET AL.	
	<b>Examiner</b> DIANE YABUT	<b>Art Unit</b> 3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 19 February 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### *Continued Examination Under 37 CFR 1.114*

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 02/19/2008 has been entered.

### *Claim Rejections - 35 USC § 102*

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 9, 17-18, 22, and 24-25 are rejected under 35 U.S.C. 102(b) as being anticipated by **McBroom** (U.S. Patent No. **6,277,108**).

Claims 1, 9, 17-18, 22, and 24-25: McBroom discloses a sheath body **140** comprising a first longitudinally extending sheath score line (“weakened portion”) running substantially along a length of said sheath body, a tearable radiopaque marker located at a distal end of said sheath body (just proximate of the distal tip of the sheath), said radiopaque marker comprising a segmented, contiguous radiopaque ring **160** or **500**

including a first marker portion, said radiopaque marker defining a gap ("perforated line") **512** running along an entirety of said first marker portion and being substantially aligned with said sheath score line ("as the sheath **140** is severed, the marker band **160** is also severed") wherein said first marker may be split apart from a remainder of said radiopaque marker along said gap, or at least one longitudinally extending marker hollow score line or notch ("perforated line") **512** running substantially along a length of said radiopaque marker, wherein said radiopaque marker may be split or torn into two or more pieces along said at least one marker score line or notch, wherein said radiopaque marker abuts said sheath by tearing said sheath (see abstract, Figures 1, 6; col. 3, line 54 to col. 4, line 14 and col. 5, lines 16-34).

### ***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 2-8, 10-16, 19-21, and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over **McBroom** (U.S. Patent No. **6,277,108**) in view of **Norlander** (U.S. Patent No. **6,562,049**).

Claims 2-5 and 10-11: McBroom discloses the claimed device including a first sheath score line located on an exterior surface of said sheath body which is aligned with a first marker score line, as well as a second marker score line or notch running substantially

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along the length of the radiopaque marker, except for a *second* sheath score line running substantially along said length of the exterior surface of said sheath body, located approximately opposite the first sheath score line, which would align with the second marker score line or notch.

Norlander teaches first and second sheath score lines **46** running substantially along a length of a sheath body **11** and located approximately opposite one another along an interior of said sheath body (Figures 6-8; col. 6, lines 50 to col. 7, line 14). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a second sheath score line or notch/gap, as taught by Norlander, to McBroom since it was known in the art that multiple score lines facilitate removal of the sheath in that it can be split more efficiently when positioned at different orientations or when one score line is not easily accessible on the opposite side.

Claims 6-8 and 12: McBroom discloses said radiopaque marker **330** being located within said sheath body **300**, and said radiopaque maker being thermally bonded and embedded in said sheath body (Figure 4; col. 4, lines 48 to col. 5, line 2).

Claims 13-16: McBroom and Norlander do not expressly disclose said first marker notch being V-shaped or U-shaped, the notch comprising first and second sidewalls, said first and second sidewalls substantially parallel to one another, and a base wall joining said first and second side walls, said base wall being substantially perpendicular to said first and second side walls. However, according to Merriam-Webster's Online Dictionary, "notch" is defined as a "V-shaped indentation" or "a rounded indentation,"

and therefore it would have been obvious to implement the above limitations to the notch of the combined device of McBroom and Norlander.

Claims 19 and 21: McBroom discloses a second marker portion and a second gap **512**, said first and second gaps defining first and second marker portions (the portions separated by the gaps), wherein said first and second marker portions are completely embedded in said sheath body and said first marker portion comprises a first marker half and said second marker portion comprises a second marker half (Figure 6; col. 5, lines 16-34).

Claims 20 and 23: McBroom discloses the radiopaque marker being made from the group consisting of particulate-laden polymer, barium sulfate, gold, platinum, and tungsten (col. 4, lines 44-47).

### ***Response to Arguments***

5. Applicant's arguments filed 02/19/2008 have been fully considered but they are not persuasive.

6. The applicant generally argues that McBroom does not disclose a tearable radiopaque marker that may be broken by tearing, but rather a marker that is slittable, or is able to be cut through by the use of a slit. However, the embodiment of Figure 6 in McBroom clearly discloses a radiopaque marker band or ring **500** that has perforations **512** which allows the band to be torn or split (see col. 5, lines 16-35).

7. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by

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combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, it was known in the art that multiple score lines facilitates removal of a sheath in that it can be split more efficiently when positioned at different orientations or when one score line is not easily accessible on the opposite side.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIANE YABUT whose telephone number is (571)272-6831. The examiner can normally be reached on M-F: 9AM-4PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Diane Yabut/  
Examiner, Art Unit 3734

/Todd E Manahan/  
Supervisory Patent Examiner, Art Unit 3731